

Fig. 1

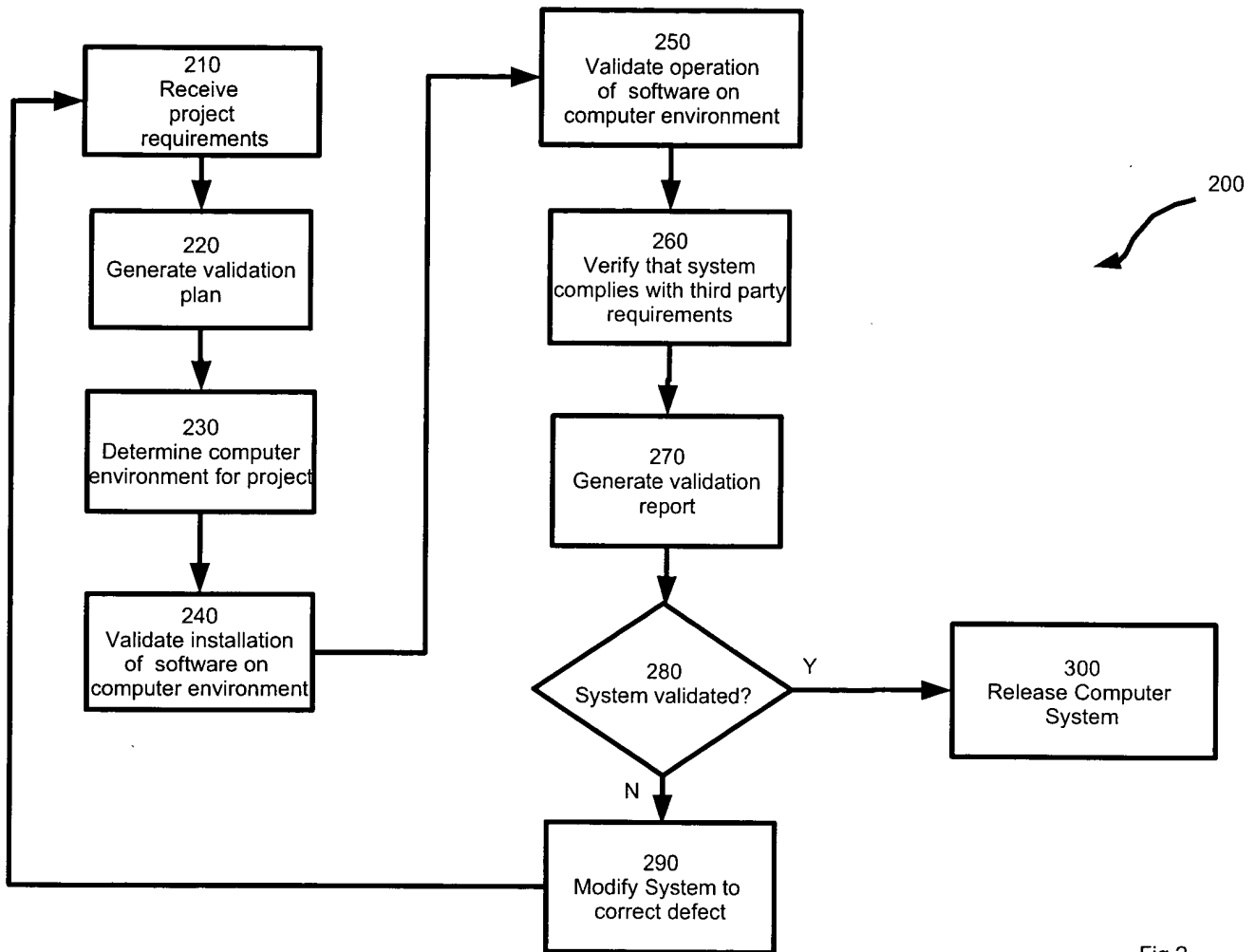


Fig.2

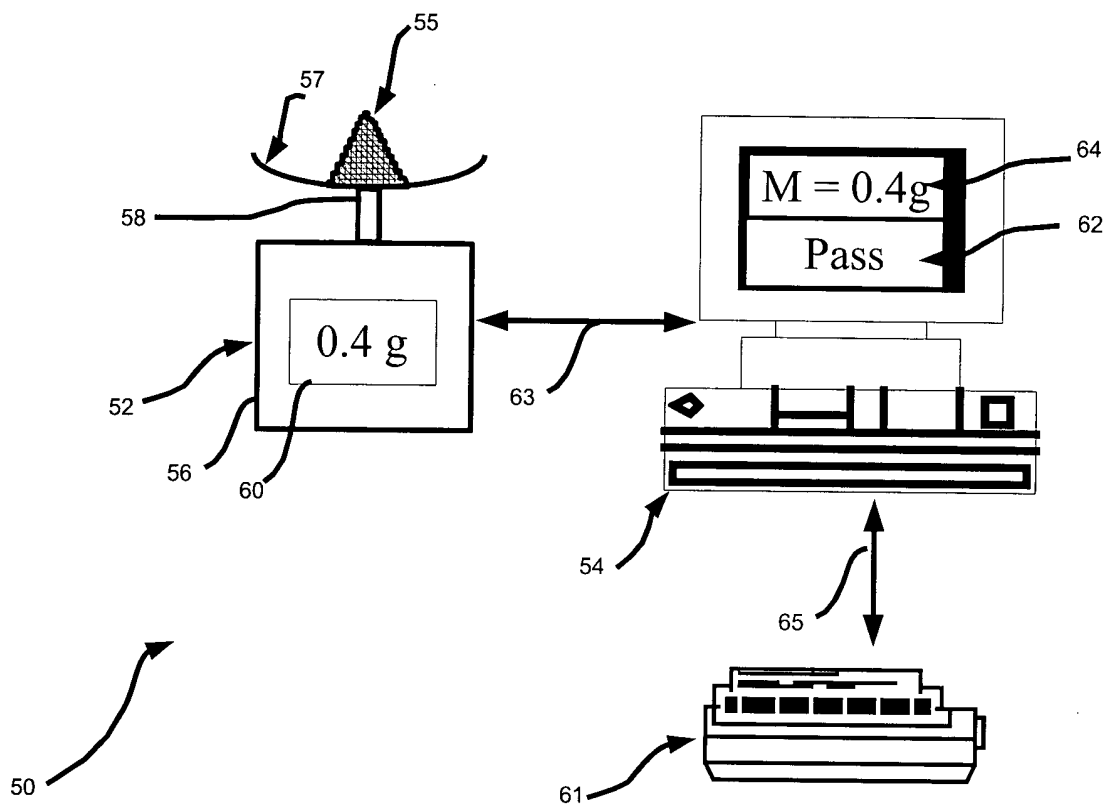


Fig.3

V

PROJECT INFORMATION

210i
210j
210k

210b Project ID:

210c Project Name:

210d Project Start Date: Completion Date:

210e Created By:

210f Vendor:

210g Name: 210g Version:

210h Company:

210h Division:

210h Department:

210h Location:

Software Components
Interface Component

Component	Detail
Production Manager	This is used by system administrators to c
Digital Signature repository	Keeps track of users signatures
Browser	This is a viewing tool to browse the data
Archive	Logging tool for measurements

Component:

Detail:

This configured by a system administrator to keep track of which users run the Weightmate, and to the level at which the user is allowed to access Weightmate during a production run of measuring masses of pharmaceutical ingredients.

R

Start
My Computer
Validator - Microsoft Visua...
Document1 - Microsoft W...
PROJECT INFORM...

11:11 AM

Fig.4

VALIDATOR

USER REQUIREMENT

Project Name: 210c

Requirement	QType
▶ Must not overwrite USB printer driver	INSTALLATION QUALIFICATION
Must work with Y/M/D date format	INSTALLATION QUALIFICATION
Must be able to run while minimized	OPERATIONAL QUALIFICATION
Must be 21 CFR Part 11 compliant	THIRD PARTY QUALIFICATION

210o 210p 210q 210r

Qualification Type:

Requirement: 210o

Start | My Computer | Validator - Microsoft Visua... | Document1 - Microsoft W... | USER REQUIREME... | 11:11 AM

Fig.5

Validation Plan

Project Name: Weightmate

220c

210c

220j Approvals

220g Periodic Review

220d Validation Scope

220l References

220h Acceptance Criteria

220e Software Constraints

220k - Test -

220f Hardware Description

System

Components in SCOPE

210i

210n

210k

210l

210m

☐ Archive

☒ Production Manager

☒ Browser

☒ Digital Signature repository

Reason for not in SCOPE

Archive not implemented at this time due to Excel Interface being used for same purpose

Interfaces

Interfaces in SCOPE

210j

☒ Excel

☐ Oracle

Reason for not in SCOPE

Oracle interface not implemented at this time due to Excel Interface being used for same purpose

Save

Print Validation Plan

Exit

220,

Fig. 6

DETAILED TEST PLAN 220k

220l

220o

220₂

210c

Project Name: **Weightmate** 220m

220n

210o

210o

210p

210q

210r

Req No	Case No	Test objective	Acceptance Criteria
1	1	The install of the USB driver for the scale	USB driver still located in OS directory
1	2	USB printer still working after install?	Print test page to USB printer
2	1	Verify OS set to Y/M/D format	View OS date/time format setting
2	2	Create sample Y/M/D records	Sample dates accurately saved
3	1	Examine behaviour while minimized	Calculations proceed during minimize?
4	1	121CFR Part 11 compliance – verification	Create sample record and save with dig

220m

210o

Test Case No: 1

Requirement No: 1

210o

Test objective: The installation of the USB driver for the scales must not overwrite the existing USB printer driver on the workstation

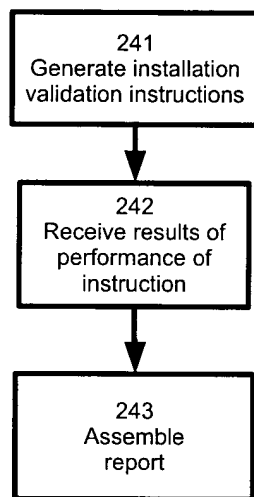
220n

Acceptance Criteria: USB Printer driver still located in OS driver directory

Comments:

Exit Add Save

Fig. 7



Step
240

Fig.8

TEST PROCEDURE

Weightmate

USER REQUIREMENT	
Requirement No	Requirement
1	Must not overwrite USB printer driver
2	Must work with Y/M/D date format

TEST CASE	
Test Case No	Test objective
1	The install of the USB driver for the scale
2	USB printer still working after install?

Step No: 0 Test Case No: 1 Requirement No: 1

Test objective: The installation of the USB driver for the scales must not overwrite the existing USB printer driver on the workstation

Test Instruction: Use install disk accompanying scales and begin installation instructions. When complete, access OS driver directory and look for the file "prnusb.drv"

Expected Results: "prnusb.drv" should still be present in OS driver directory.

Add Save Exit

Validator Print Screen.do... Validator - Microsoft Visua...

4:13 PM

Fig. 9

Incident Report Form

Project Name: Weightmate

IncidentID	IncidentDesc	CorrectiveAction	Pass/Fail
1	USB Printer driver not found as expected	Investigate whether printer	Fail

Incident ID: 1 Test Case No: 1 Requirement No: 1

Objective: The installation of the USB driver for the scales must not overwrite the existing USB printer driver on the workstation

Incident: USB Printer driver not found as expected

Corrective Action: Investigate whether printer driver can be reinstalled.

Pass/Fail: Fail

Add Save Print Incident Report Form Exit

Fig. 10

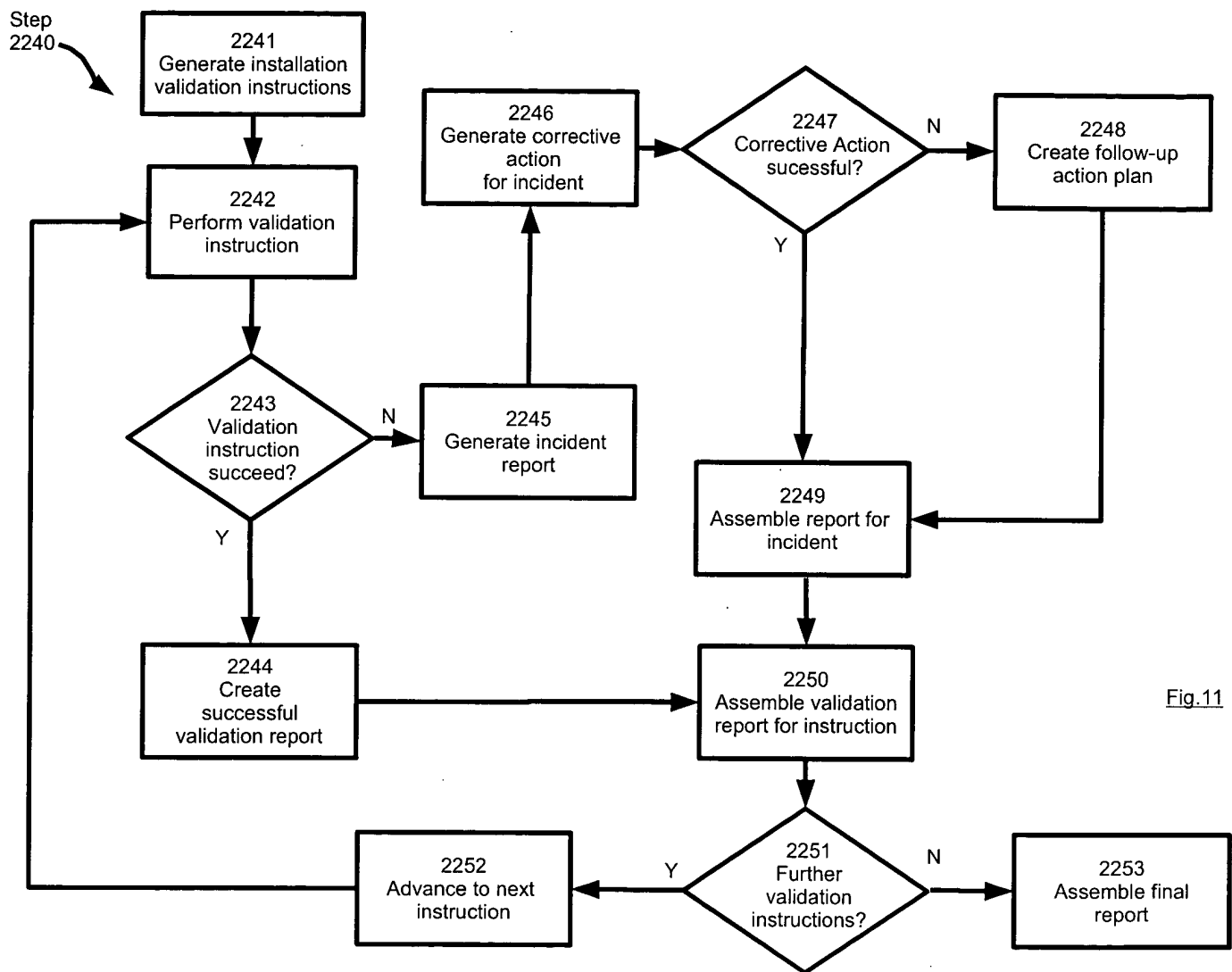
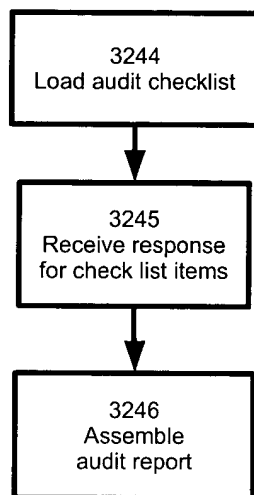
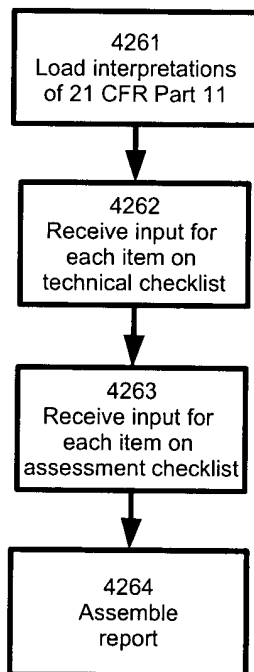


Fig.11



3240

Fig.12



4260

Fig.13

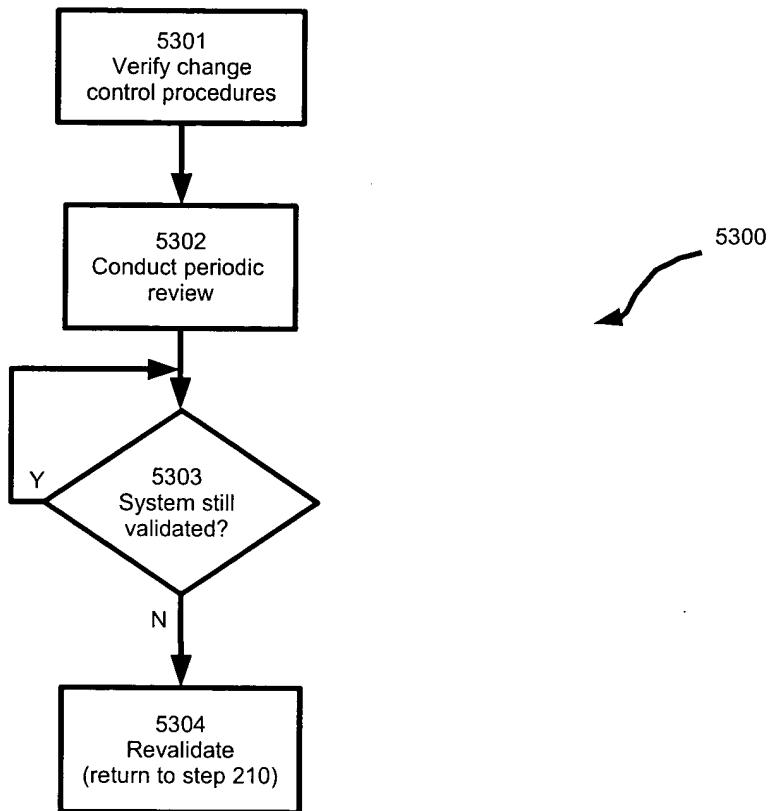


Fig.14

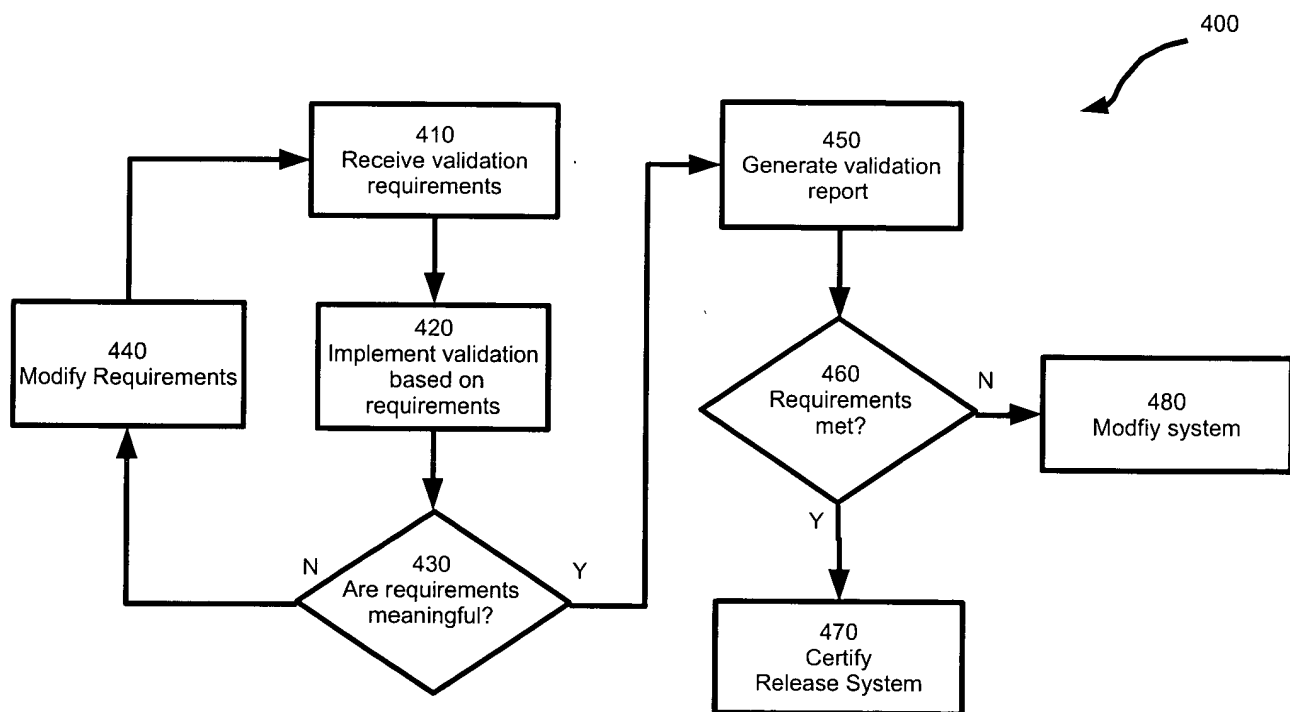


Fig.15